

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Sherry Leonard *et al.*

Serial No.: 08/956,518

Group No.: 1645

Filed: 10/23/97

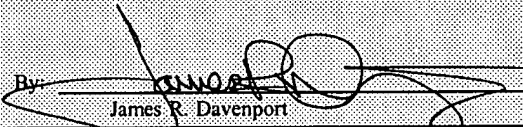
Examiner: R. Hayes

Entitled: ALPHA-7 NICOTINIC RECEPTOR



STATEMENT OF APPLICANTS  
UNDER 37 CFR § 1.251

Gary Kunz  
United States Patent & Trademark Office  
Arlington, VA 22202


CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.10	
I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being deposited with the U.S. Postal Service in an envelope as "Express Mail Post Office to Addressee" Mailing Label Number EV 001 613 469 US, addressed to: Gary Kunz, United States Patent & Trademark Office, Arlington, VA 22202.	
Dated: <u>May 13, 2002</u>	By:  James R. Davenport

Sir:

The copy of the listed documents is a complete and accurate copy of Applicants' record of all of the correspondence between the Office and Applicants, for U.S. Patent Appln. Serial No. 08/956,518. Applicants are not aware of any correspondence between the Office and Applicants, for U.S. Patent Appln. Serial No. 08/956,518, that is not among Applicants' records.

Signing on behalf of:

Dated: May 13, 2002

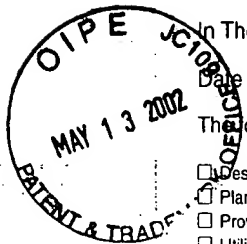
  
David A. Casimir  
Registration No. 42,395

MEDLEN & CARROLL, LLP  
101 Howard Street, Suite 350  
San Francisco, California 94105  
415.904.6500

Serial No.: 08/956,518

MC File No.: UTC-03042

By: KTM



In The Matter of the Application Of: SHERRY LEONARD et al.

Date Mailed: 07/15/99

Due Date: 07/09/99

The following has been received in the U.S. Patent and Trademark Office on the date stamped hereon:

- |   |  |   |                                    |
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| <input type="checkbox"/> Utility Patent Application _____ Pages                           | <input type="checkbox"/> Trademark Renewal Application                     |   |                                    |
| <input type="checkbox"/> Information Disclosure Statement                                 | <input type="checkbox"/> Section 8 & 15 Affidavits                         | <input checked="" type="checkbox"/> Check(s): \$ 110.00           |                                    |
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| References Contained Thereon  | <input type="checkbox"/> Declaration/Oath/Affidavits                       |   |                                    |
| <input type="checkbox"/> Form PTO-1533 (Not. of Missing Parts)                            | <input type="checkbox"/> Drawings: _____ Sheet(s)                          |   |                                    |
| <input type="checkbox"/> Certificate Re: Sequence Listing                                 | <input type="checkbox"/> Formal <input type="checkbox"/> Informal          |   |                                    |
| <input type="checkbox"/> Sequence Listing in Paper Copy and on Computer Readable Diskette | <input type="checkbox"/> Power of Attorney _____                           |   |                                    |
| <input type="checkbox"/> Form PTOL-85B (Issue Fee Transmittal)                            | <input type="checkbox"/> Form PTO-1594/1595                                |   |                                    |
| <input type="checkbox"/> Form PTO-1050 (Cert. of Correction)                              | <input type="checkbox"/> Assignment  |   |                                    |
| <input type="checkbox"/> Maintenance Fee Transmittal Form                                 | <input type="checkbox"/> Small Entity Declaration                          |   |                                    |
| <input type="checkbox"/> Reexamination Request  | <input checked="" type="checkbox"/> Amendment/Response to Restriction Req. |   |                                    |
| <input type="checkbox"/> PCT Application _____ Pages                                      | <input checked="" type="checkbox"/> Extension of Time Req.: 1 Month(s)     |   |                                    |
| <input type="checkbox"/> Chapter II Demand  | <input type="checkbox"/> Notice of Appeal                                  |   |                                    |
|   | <input type="checkbox"/> Petition _____                                    |   |                                    |

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28422

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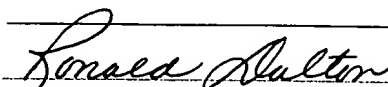
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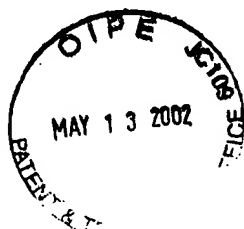
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INVOICE # 13948

response to restriction requirement



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: Sherry Leonard *et al.*

Serial No.: 08/956,518

Group No.: 1645

Filed: 10/23/97

Examiner: R. Hayes

Entitled: **ALPHA-7 NICOTINIC RECEPTOR**



**RESPONSE TO NOTICE TO COMPLY WITH  
REQUIREMENTS FOR PATENT APPLICATIONS  
CONTAINING NUCLEOTIDE SEQUENCE**

Assistant Commissioner for Patents  
Washington, D.C. 20231

<b>CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)(1)(i)(A)</b>	
<small>I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.</small>	
Dated: <u>April 1, 1999</u>	By: <u>Marlene Garitano</u> <small>Marlene Garitano</small>

Sir:

In response to the Notice to Comply mailed 03/23/99, please make the following amendments:

**IN THE SPECIFICATION:**

Please replace pages "89 to 122" with new pages --89 to 122-- (attached hereto), which contain the "substitute" Sequence Listing in this patent application.


**R E M A R K S**

This amendment reflects the introduction of a "substitute" Sequence Listing, finds support in the application and Figures, and does not introduce new matter.

**CONCLUSION**

Should the Examiner have any questions regarding the above or believe that a telephone interview would aid in the prosecution of this application, Applicants encourage the Examiner to call the undersigned collect.

Dated: 1 April 1999

  
Kamrin T. MacKnight  
Registration No. 38,230

MEDLEN & CARROLL, LLP  
220 Montgomery Street, Suite 2200  
San Francisco, California 94104  
415.705.8410

**NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES**

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):



- ☐ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.
- ☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☒ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☐ 7. Other: \_\_\_\_\_

**COPY****Applicant Must Provide:**

- ☒ An ~~initial~~ or substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☒ An ~~initial~~ or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

For CRF Submission Help, call (703) 308-4212

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Suite 2200  
San Francisco, CA 94104

# DISKETTE ENCLOSED



Applicant: Sherry Leonard *et al.*

Title: ALPHA-7 NICOTINIC RECEPTOR

Application No.: 08/956,518

Computer Readable Form:

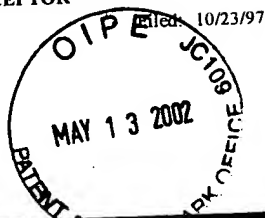
Medium Type: 3.5" 1.44 Mb Floppy Disk

Computer: IBM PC Compatible

Operating System: PC-DOS/MS-DOS

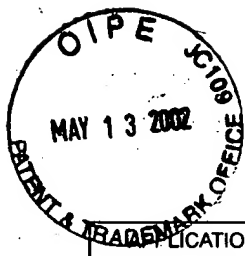
Software: PatentIn Ver. 2.0

Date Data Recorded: 03/31/99



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/956,518

10/23/97

LEONARD

S

UTC-03042

HM12/0609

EXAMINER

HAYES, R

ART UNIT

PAPER NUMBER

1645

DATE MAILED:

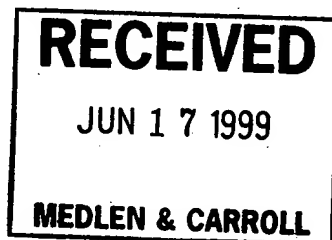
06/09/99

KAMRIN T. MACKNIGHT  
MEDLEN & CARROLL  
220 MONTGOMERY STREET  
SUITE 2200  
SAN FRANCISCO CA 94104

*Resp. 7/9/99 RLD*

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks



# Office Action Summary

Application No.  
08/956,518

Applicant(s)  
Leonard et al

Examiner  
Robert C. Hayes

Group Art Unit  
1645



☐ Response to communication(s) filed on \_\_\_\_\_

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-25 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☐ Claim(s) \_\_\_\_\_ is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-25 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1645

## **DETAILED ACTION**

### ***Election/Restriction***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1, 3-8, drawn to nucleic acid molecules encoding the alpha-7 nicotinic receptor, vectors and host cells, classified in class 435, subclass 325.
  - II. Claim 2, drawn to alpha-7 nicotinic receptor polypeptides, classified in class 530, subclass 350.
  - III. Claims 9-13, drawn to a method of detecting alpha-7 nicotinic receptor polynucleotides in a biological sample, classified in class 435, subclass 5.
  - IV. Claim 14-25, drawn to method of amplifying alpha-7 nicotinic receptor polynucleotides, classified in class 435, subclass 91.2.

2. The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relation of Inventions" in MPEP 806.05 for inventive groups that are directed to different products; restriction is deemed proper because these products appear to constitute patently distinct inventions for the following reason:

Groups I-II are directed to products that are physically and functionally distinct that involve nucleic acids or proteins. Each of these products can be prepared by different processes, such as though chemical synthesis or isolation from natural sources using various isolation/

Art Unit: 1645

purification procedures. For example, the polypeptides of Group II are fundamentally different molecules than the polynucleotides of Group I, which in turn can be used to clone proteins, detect expression of the gene product, or used as therapeutic agents in gene therapy. Alternatively, the proteins of Group II can be utilized to generate antibodies. It is pointed out that there is a proper distinction between these groups, since each product is not required in order for the other to exist. Thereby, these groups are distinct and separable for the reasons stated.

Groups I and III-IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P.

§ 806.05(h)). In the instant case, the nucleic acids can be used in materially different processes, such as to encode the full length protein or used in gene therapy. The method of detecting and amplifying nucleic acid molecules requires primers and appropriate salt and hybridization conditions, which are not required for the products of Group I. It is further noted that the methods of Groups III & IV do not require the products of Group II.

Although there are no provisions under the section for "Relation of Inventions" in MPEP 806.05 for inventive groups that are directed to different methods; restriction is deemed proper because these methods appear to constitute patently distinct inventions for the following reason:

Art Unit: 1645

Groups III-IV are directed to methods of detecting or amplifying nucleic acid molecules. Each of the methods require physically and functionally distinct elements. For example, the method for detecting the presence of a nucleic acid molecule is distinguished from the method for amplifying a nucleic acid by PCR of Group IV, in that the diagnostic method of Group III requires inclusion of labeled nucleotides, unlike the PCR method of Group IV, which requires appropriate primers. Moreover, the method involving generation of PCR reaction products require purification protocols specific to isolating and detecting small nucleic acid molecules, unlike the method of Group III. These inventions are, therefore, patentably distinct, since one is not required for the other.

3. Because these inventions are distinct for the reasons given above, they have acquired a separate status in the art as shown by their different classification, and the non-coextensiveness of the search and examination for each group would constitute an undue burden on the examiner to search and consider all the separable groups, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently

Art Unit: 1645

named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

**4. Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Donald E. Adams, Ph.D., Supervisory Patent Examiner at Donald.Adams@uspto.gov or 703-308-0570. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Robert C. Hayes, Ph.D.  
June 8, 1999



ANTHONY C. CAPUTA  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600



# OPEN HOUSE PROGRAM



B10

Technology Center 1000  
August 24, 2002

**Location:**

Crystal Room  
1999 Jefferson Davis Highway  
Arlington, VA 22202

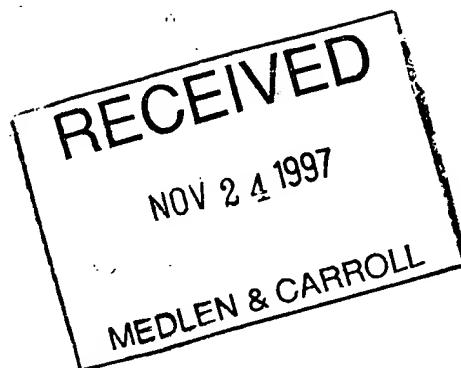
**Cost:** \$70 (includes: program, lunch on 8/24, reception on 8/25)

Registration at 8, program begins at 8:30  
August 26, program begins at 8

**Program Includes:**

- Patent Operations Issues
- Quality Update
- Biotech Policy
- BIO Strategic Planning
- Patent Automation Initiatives
- Town Hall Meeting
- Luncheon Speech by Q. Todd Dickinson Acting Commissioner of Patents and Trademarks
- Appeals and Interferences
- Design Issues
- Tours of the Technology Center
- Demonstrations of Automation Tools including PatentIt
- Panels of SPEs on current topics

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PRIOR ART STATEMENT DUE 3 MONTHS 1/23/98  
FOREIGN FILING LETTER DUE 4/23/98  
6 MONTHS UTILITY / 3 MONTHS DESIGN 10/23/98  
FOREIGN FILING DEADLINE 7/23/99  
12 MONTHS UTILITY / 6 MONTHS DESIGN 7/23/99  
TWENTY-ONE MONTHS SUSPENSE DATE 7/23/99  
RLD

Serial No.: \_\_\_\_\_

MC File No.: UTC-3042

By: km

In The Matter of the Application Of: LEONARD E. FT. PA. AL.

Date Mailed: 10/23/97 08/956518 U.S. PTO Due Date: \_\_\_\_\_

The following has been received in the U.S. Patent and Trademark Office on the date stamped hereon:

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| <input type="checkbox"/> Prov. Patent Application _____ Pages                             | <input type="checkbox"/> Statement of Use                                       | <input checked="" type="checkbox"/> Cert. of Express Mailing Label No.: <u>EM121692361 US</u> |
| <input checked="" type="checkbox"/> Utility Patent Application _____ Pages                | <input type="checkbox"/> Trademark Renewal Application                          | <input checked="" type="checkbox"/> Check(s): <u>\$ 491</u>                                   |
| <input type="checkbox"/> Information Disclosure Statement                                 | <input type="checkbox"/> Section 8 & 15 Affidavits                              | <input checked="" type="checkbox"/> Deposit Account Authorization                             |
| <input type="checkbox"/> Form PTO-1449 and Copies of _____                                | <input type="checkbox"/> Specimens  |   |
| <input type="checkbox"/> References Contained Thereon                                     | <input checked="" type="checkbox"/> Declaration/Oath/Affidavits <u>(w/enc.)</u> |   |
| <input type="checkbox"/> Form PTO-1533 (Not. of Missing Parts)                            | <input checked="" type="checkbox"/> Drawings: <u>10</u> Sheet(s)                |   |
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| <input type="checkbox"/> Sequence Listing in Paper Copy and on Computer Readable Diskette | <input checked="" type="checkbox"/> Power of Attorney <u>(w/enc.)</u>           |   |
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| <input type="checkbox"/> Maintenance Fee Transmittal Form                                 | <input type="checkbox"/> Small Entity Declaration                               |   |
| <input type="checkbox"/> Reexamination Request  | <input type="checkbox"/> Amendment/Response                                     |   |
| <input type="checkbox"/> PCT Application _____ Pages                                      | <input type="checkbox"/> Extension of Time Req.: _____ Month(s)                 |   |
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BOX PATENT APPLICATION

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22740

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23 October 1997

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Description: PTO Filing Fee

23 October 1997

\$491.00